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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Effect of introducing a regional 24/7 primary percutaneous coronary intervention service network on treatment outcomes in patients with ST segment elevation myocardial infarction

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Abstract

Background: In patients with acute ST segment elevation myocardial infarction (STEMI), primary percutaneous coronary intervention (PCI) is the preferred reperfusion method over fibrinolysis, if it is performed in a timely fashion by an experienced team in a centre with on-site primary PCI service. Treatment delay due to patient transfer to the cardiac catheterisation laboratory is an important limitation of mechanical reperfusion in STEMI patients.

Aim: To analyse treatment outcomes in STEMI patients hospitalised in a regional hospital in Tarnow before and after introduction of a 24/7 primary PCI service.

Methods: Enrolment into the registry continued for 12 months before introduction of a 24/7 primary PCI service (Period I: 19.04.2004–19.04.2005) and 15 months after introduction of a 24/7 primary PCI service (Period II: 8.08.2005–19.10.2006). Overall, 226 STEMI patients were analysed, including 115 patients in Period I and 111 patients in Period II. STEMI patients in Period I received conservative treatment (n = 59), pharmacoinvasive treatment (a half dose of alteplase, a full dose of abciximab, and transfer to a 24/7 primary PCI reference centre: n = 32) or fibrinolysis with streptokinase (n = 24), while all patients in Period II underwent primary PCI on the first day of hospitalisation. Occurrence of cardiovascular deaths, non-fatal recurrent infarctions, and revascularisation with PCI or coronary artery bypass grafting was evaluated in the two groups during 1-year follow-up.

Results: Reperfusion therapy was used in 48.7% of STEMI patients in Period I (pharmacoinvasive treatment in 27.8% and fibrinolysis in 20.9%), and all patients in Period II underwent primary PCI. In-hospital mortality among STEMI patients in Period I was significantly higher than in Period II (23.5% vs. 5.4%, $p < 0.001$), and it was 23.7% in patients managed conservatively. The hazard ratio for Period II compared to Period I was 0.14 (95% CI 0.03–0.62, $p = 0.009$). A benefit of invasive treatment was seen during 1 year of follow-up (mortality 26.1% in Period I vs. 9.0% in Period II, $p = 0.001$). Invasive treatment was also associated with a shorter hospital stay.

Conclusions: Introduction of a 24/7 primary PCI regional service (STEMI network) led to improved accessibility of invasive diagnosis and treatment and increased reperfusion treatment rates, resulting in reduced in-hospital and 1-year mortality among STEMI patients.

Key words: myocardial infarction, registry, primary percutaneous coronary intervention, cardiovascular mortality, STEMI network

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INTRODUCTION

Primary percutaneous coronary intervention (PCI) is the preferred approach to reperfusion therapy over fibrinolysis if it can be performed in a timely fashion by an experienced team in a cardiac catheterisation facility providing a 24/7 PCI service [1]. Thus, delay related to transferring ST segment eleva-

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tion myocardial infarction (STEMI) patients to a PCI-capable hospital may be a limitation of this treatment approach. To limit delays to primary PCI, hospital networks are created that comprise a core facility providing a 24/7 PCI service, a number of cooperating non-PCI-capable hospitals, and emergency medical services. This shortens the time to reperfusion (i.e., primary PCI) and reduces mortality among STEMI patients. European and American guidelines recommend developing such networks as the basic system of healthcare organisation in the management of STEMI [1, 2].

On August 8, 2005, a 24/7 primary PCI service was initiated in a regional hospital in Tarnow, providing PCI services for the city of Tarnow and a regional network of cooperating non-PCI-capable hospitals.

The aim of this study was to evaluate outcomes in STEMI patients hospitalised in the regional hospital in Tarnow before and after initiation of a 24/7 primary PCI service.

METHODS

The study group included consecutive STEMI patients presenting to the E. Szczeklik Specialist Hospital in Tarnow, Poland.

The diagnosis of STEMI was based on generally accepted criteria (typical chest pain, new ST segment elevation or new left bundle branch block in the electrocardiogram [ECG]).

The study was a prospective registry, with data collection from two periods, from April 19, 2004 to April 19, 2005 (Period I, before initiation of a 24/7 primary PCI service), and from August 8, 2005 to October 19, 2006 (Period II, after initiation of a 24/7 primary PCI service).

During Period I, patients with the initial diagnosis of an acute coronary syndrome were admitted to the cardiology unit in Tarnow or, in case of STEMI presentation within 12 h, they were transferred directly from the emergency room to the Department of Haemodynamics and Angiocardiography at the Institute of Cardiology, Jagiellonian University Medical College in Krakow, following a telephone consultation with a cardiologist on duty who made a decision to proceed with invasive coronary angiography. Due to expected significant transfer-related delay, a pharmacoinvasive strategy was employed in these patients, including initial drug therapy (aspirin, a reduced dose of unfractionated heparin, full dose of a glycoprotein IIb/IIIa inhibitor abciximab, and a half dose of alteplase) before transfer for PCI. STEMI patients who stayed in the local hospital in Tarnow received fibrinolytic therapy (streptokinase at a standard dose of 1.5 million units intravenously over 60 min) if not contraindicated, or received medical therapy (i.e., no reperfusion therapy) and were referred for invasive coronary angiography at the local cardiac catheterisation laboratory during the index hospitalisation.

During Period II, STEMI patients underwent immediate coronary angiography and primary PCI.

Data were collected during hospitalisation using medical charts and records according to the established standards and entered to the registry database. One-year follow-up data were collected by a telephone interview with patients or their families. In this way, complete 1-year follow-up data were obtained for both study groups.

We analysed in-hospital data (treatment outcomes including the following endpoints: cardiovascular death, recurrent non-fatal infarction, and PCI or coronary artery bypass grafting [CABG] due to recurrent ischaemia within the territory of the vessel treated with PCI) and 1-year follow-up data. A combined endpoint was defined as the sum of all individual endpoints.

The study was approved by a Bioethics Committee at the Regional Medical Chamber in Tarnow.

Statistical analysis

Continuous variables were described with arithmetic means and standard deviation. The Student *t* test or non-parametric Mann-Whitney test was used to compare mean values of continuous variables in the two study groups. Categorical variables were reported as numbers and percentages, and their distributions in the two study groups were compared using the χ^2 test or exact Fisher test. Survival was estimated using the Kaplan-Meier method, and log rank test was used to compare the two study groups. Hazard ratio (HR) was estimated using a Cox regression model. $P < 0.05$ was considered statistically significant. All calculations were performed using the STATISTICA 8 software (StatSoft, Poland).

RESULTS

The registry included 226 STEMI patients who were divided into two groups depending on whether data were collected before (Group I, n = 115) or after (Group II, n = 111) initiation of a 24/7 primary PCI service.

Comparison of patient groups

Patients in Group I had more advanced peripheral atherosclerosis (intermittent claudication, a history of stroke). Patients in Group I presented later (with longer time from the onset of chest pain to hospitalisation) and had lower blood pressure on admission, with no differences in the Killip classification (Table 1). We found no differences regarding in-hospital drug therapy, except for more frequent use of clopidogrel in Group II. In Group II, duration of hospital stay was shorter and PCI rate was higher compared to the period before initiation of a 24/7 PCI service. In Period II, in-hospital and 1-year cardiovascular mortality was significantly reduced compared to Period I. We found no differences in the rates of recurrent non-fatal infarction and repeated PCI/CABG (Table 2, Figs. 1, 2).

Treatment outcomes in Group I

During Period I, only 27.8% of STEMI patients underwent mechanical reperfusion on the first day of hospital stay, 20.9% of patients were treated with fibrinolysis, and the remaining

Table 1. Study group characteristics

	STEMI I	STEMI II	P
Number of patients	n = 115	n = 111	
Age, mean ± SD [years]	63.5 ± 12.7	63.6 ± 11.2	0.94
Men [%]	73.9	68.5	0.37
Past medical history:			
Hypercholesterolaemia [%]	21.7	32.4	0.07
Hypertension [%]	67.8	64.9	0.64
Smoking [%]	46.1	41.4	0.48
Previous MI [%]	13.9	14.4	0.91
Previous PCI [%]	3.5	2.7	0.74
Previous CABG [%]	0.0	0.0	–
Symptoms of heart failure [%]	5.2	0.9	0.06
Previous stroke [%]	9.6	2.7	0.032*
Peripheral arterial disease [%]	11.3	3.6	0.028*
Diabetes [%]	16.5	19.8	0.31
Renal failure [%]	0.0	0.0	–
Hospitalisation:			
Heart rate on admission [bpm]	82.8 ± 19.5	83.3 ± 17.8	0.84
Systolic BP on admission [mm Hg]	134.8 ± 24.9	145.8 ± 30.5	0.004*
Diastolic BP on admission [mm Hg]	84.9 ± 15.8	89.7 ± 18.1	0.042*
Killip class on admission [%]:			
1 + 2	87.0	89.0	
3 + 4	13.0	11.0	0.64
Time from the onset of pain to admission [h]:			
0–3	33.0	29.3	
3–6	21.4	39.4	
6–12	12.6	26.3	< 0.001*
12–24	14.6	4.0	
> 24	18.4	1.0	
Anterior wall infarction [%]	30.9	42.3	0.12
LVEF during hospitalisation [%]	50.1 ± 11.6	49.4 ± 12.9	0.72
GFR (mL/min/1.73 m^2): < 60	13.5	14.7	0.60
Duration of hospital stay [days]	11.1 ± 4.6	6.0 ± 2.7	< 0.001*
Fibrinolytic therapy [%]	20.9	0.0	<0.001*
Coronary angiography during hospitalisation [%]	59.1	100.0	< 0.001*
Single-vessel disease [%]	48.5	36.9	0.13
PCI during hospitalisation [%]	50.4	100.0	< 0.001*

*Statistical significance; BP — blood pressure; CABG — coronary artery bypass grafting; GFR — glomerular filtration rate; LVEF — left ventricular ejection fraction; MI — myocardial infarction; PCI — percutaneous coronary intervention; SD — standard deviation; STEMI — ST elevation myocardial infarction

patients were managed conservatively. In Group I, coronary angiography was performed during the index hospitalisation in only 59.1% of patients, as the remaining patients did not consent to invasive coronary angiography. The lowest in-hospital cardiovascular mortality was found among patients receiving pharmacoinvasive treatment.

Comparison of Group I patients treated with fibrinolysis and patients not receiving reperfusion therapy and Group II patients

During Period II, all STEMI patients were treated with mechanical reperfusion. Duration of hospital stay was shorter, and patient survival was significantly higher compared to patients

Table 2. Treatment outcomes

	STEMI I	STEMI II	P
Number of patients	n = 115	n = 111	
CV death during hospitalisation [%]	23.5	5.4	< 0.001*
CV death at 1 year [%]	26.1	9.0	0.001*
Recurrent infarction at 1 year [%]	4.4	3.6	0.77
PCI at 1 year [%]	2.6	3.6	0.67
CABG at 1 year [%]	0.9	5.4	0.049*
Death + recurrent infarction + PCI/CABG at 1 year [%]	29.6	12.6	0.002*

*Statistical significance; CABG — coronary artery bypass grafting; CV — cardiovascular; PCI — percutaneous coronary intervention; STEMI — ST elevation myocardial infarction

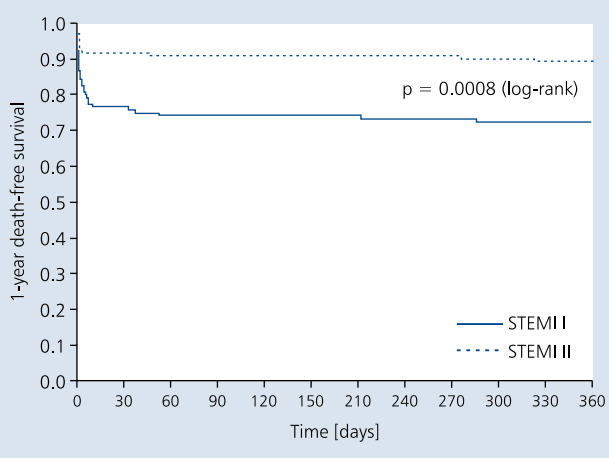

Figure 1. Kaplan-Meier curves for overall survival in ST elevation myocardial infarction (STEMI) patient groups (Period I vs. Period II)

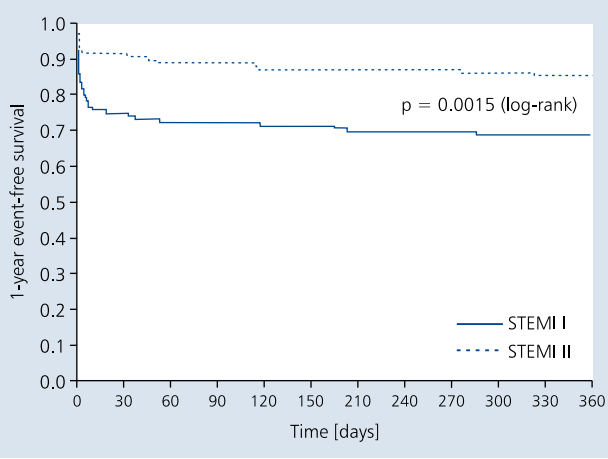

Figure 2. Kaplan-Meier curves for survival free from the combined endpoint in ST elevation myocardial infarction (STEMI) patient groups (Period I vs. Period II)

treated with fibrinolysis and patients not receiving reperfusion therapy during Period I (Tables 3, 4).

A multivariate Cox regression model was developed to determine HR adjusted for a history of ischaemic heart disease, previous stroke, peripheral arterial disease, time from the onset of symptoms to hospitalisation, and systolic blood pressure on admission. HR for Period II compared to Period I was 0.14 (95% CI 0.03–0.62, p = 0.009), and thus the risk of dying during the first 30 days after the procedure was significantly lower in Period II compared to Period I. Unadjusted HR was 0.08 (95% CI 0.02–0.35, p = 0.001).

DISCUSSION

Our findings indicate a significant effect of introducing a regional primary PCI service network on the reduction of mortality in STEMI patients.

The European Society of Cardiology guidelines on the management of STEMI recommend primary PCI as the preferred reperfusion therapy if it can be performed in a timely fashion by an experienced team [1]. However, as indicated by the registry data, keeping the recommended maximum PCI delay may be difficult in practice, particularly when STEMI patients present to non-PCI-capable hospitals [3, 4]. In addition, despite established benefits from primary PCI, this approach is still not commonly used and a large number of STEMI patients receive no reperfusion therapy at all [5, 6]. Delaying mechanical reperfusion leads to worse treatment outcomes. In the analysis by De Luca et al. [7], each 30-min delay was associated with a 7.5% relative increase in 1-year mortality. Similarly, an increase in 6-month mortality in relation to a delay of reperfusion therapy was found in an analysis of the GRACE registry findings [8]. Of importance, available data indicate that the need for patient transfer to a hospital providing 24/7 PCI capability may result in such a delay of reperfusion therapy that its benefit over immediate fibrinolysis is largely reduced or even abolished. In the analysis by Pinto et al. [9], mortality difference between patients treated with primary PCI or fibrinolysis was eliminated when the delay of PCI (in relation to fibrinolysis) was more than 114 min. This time was different in different patients subgroups and was related to

Table 3. Hospital treatment data and outcomes in subgroups. STEMI I group (fibrinolytic therapy vs. medical therapy, pharmaco-invasive therapy vs. medical therapy). Medical therapy defined as no coronary intervention during the first day of hospitalisation

	Fibrinolytic therapy	Medical therapy	P	Pharmaco-invasive therapy	Medical therapy	P
Number of patients	n = 24	n = 59		n = 32	n = 59	
Duration of hospital stay [days]	10.2 ± 8.0	9.7 ± 5.6	0.78	9.8 ± 5.5	9.7 ± 5.6	0.94
Fibrinolytic therapy [%]	37.5	23.7	0.20	9.4	23.7	0.09
Coronary angiography during hospitalisation [%]	20.8	52.5	0.008*	100.0	52.5	< 0.001*
Single-vessel disease [%]	20.8	25.4	0.66	40.6	25.4	< 0.001*
PCI during hospitalisation [%]	16.7	37.3	0.07	100.0	37.3	< 0.001*
CV death during hospitalisation [%]	37.5	23.7	0.20	9.4	23.7	0.09
CV death at 1 year [%]	37.5	30.5	0.54	9.4	30.5	0.022*
Recurrent infarction at 1 year [%]	4.2	3.4	0.86	6.3	3.4	0.52
PCI at 1 year [%]	4.2	0.0	0.11	6.3	0.0	0.05
CABG at 1 year [%]	0.0	1.7	0.52	0.0	1.7	0.46
Death + recurrent infarction + PCI/CABG at 1 year [%]	41.7	32.2	0.41	15.6	32.2	0.09

*Statistical significance; CABG — coronary artery bypass grafting; CV — cardiovascular; PCI — percutaneous coronary intervention; STEMI — ST elevation myocardial infarction

Table 4. Hospital treatment data and outcomes in subgroups (continued). STEMI I and STEMI II groups (fibrinolytic therapy in Period I vs. primary PCI in Period II, medical therapy in Period I vs. primary PCI in Period II). Medical therapy defined as no coronary intervention during the first day of hospitalisation

	STEMI I Fibrinolytic therapy	STEMI II Primary PCI	P	STEMI I Medical therapy	STEMI II Primary PCI	P
Number of patients	n = 24	n = 111		n = 59	n = 111	
Duration of hospital stay [days]	10.2 ± 8.0	6.0 ± 2.7	< 0.001*	9.7 ± 5.6	6.0 ± 2.7	< 0.001*
Fibrinolytic therapy [%]	37.5	0.0	< 0.001*	23.7	0.0	< 0.001*
Coronary angiography during hospitalisation [%]	20.8	100.0	< 0.001*	52.5	100.0	< 0.001*
Single-vessel disease [%]	20.8	36.9	< 0.001*	25.4	36.9	< 0.001*
PCI during hospitalisation [%]	16.7	100.0	< 0.001*	37.3	100.0	< 0.001*
CV death during hospitalisation [%]	37.5	5.4	< 0.001*	23.7	5.4	< 0.001*
CV death at 1 year [%]	37.5	9.0	< 0.001*	30.5	9.0	< 0.001*
Recurrent infarction at 1 year [%]	4.2	3.6	0.90	3.4	3.6	0.94
PCI at 1 year [%]	4.2	3.6	0.90	0.0	3.6	0.14
CABG at 1 year [%]	0.0	5.4	0.24	1.7	5.4	0.25
Death + recurrent infarction + PCI/CABG at 1 year [%]	41.7	12.6	0.001*	32.2	12.6	0.002*

*Statistical significance; CABG — coronary artery bypass grafting; CV — cardiovascular; PCI — percutaneous coronary intervention; STEMI — ST elevation myocardial infarction

the onset of clinical symptoms, patient age, and infarct localisation. In the analysis by De Luca et al. [10], the difference in mortality was abolished when PCI was delayed by more than 180 min, while in the metaanalysis by Boersma et al. [11], PCI had an advantage over fibrinolysis despite a treatment delay of 120 min (larger delays were not observed). To reduce PCI delays due to logistic problems, a concept of regional STEMI treatment network was developed, comprising a core facility with 24/7 PCI capability, a number of cooperating non-PCI-capable hospitals, and emergency medical services

system [1, 2, 12, 13]. As indicated by our findings, such organisation of care increases accessibility of reperfusion therapy (by increasing the rate of primary PCI) among STEMI patients and reduces mortality in this patient population. Similarly to our study, Saia et al. [14] showed that introduction of regional primary PCI network was associated with an increased rate of reperfusion therapy among STEMI patients by increasing the proportion of patients treated with primary PCI, while the rate of fibrinolytic therapy was reduced. Introduction of this treatment network was also associated with a mortality reduction. Similar associations were noted in an analysis of the Vienna STEMI Registry [15]. In our registry, the highest cardiovascular mortality in Period I was observed among patients who did not receive pharmacoinvasive therapy (treated with on-site fibrinolysis or not receiving reperfusion therapy). This may be largely related to a high risk profile of these patients, but also unavailability of primary PCI which might be the treatment of choice in many of these patients despite their concomitant conditions. If transfer within the recommended time limits is not possible, an intermediate solution may be so-called pharmacoinvasive strategy that encompasses initial lytic treatment followed by immediate patient transfer to a hospital with 24/7 PCI capability with a view to coronary angiography and possibly PCI. This treatment model was employed in the first period of our registry [16, 17]. Benefits of such management strategy compared to fibrinolysis without immediate patient transfer to a hospital with 24/7 PCI capability (transfer only for rescue or elective PCI) were shown in the CARESS in AMI and TRANSFER AMI studies [18, 19]. Of note, however, such an approach also has some limitations, for example related to contraindications to fibrinolysis and in practice it is most commonly employed in patients with low bleeding risk.

Limitations of the study

The major limitation of our study was a low number of patients. The study was a non-randomised registry. However, performing a randomised study to evaluate the effect of STEMI care organisation does not seem feasible [20]. A registry that includes consecutive hospitalised patients allows evaluation of treatment outcomes during everyday clinical practice. In our registry, we did not evaluate delays from the first medical contact to administration of various reperfusion therapies during the study periods. Although these data are several years' old, our findings remain important and highlight benefits of reducing PCI delays by development of hospital networks that include a core PCI facility, a number of cooperating non-PCI-capable hospitals, and appropriately prepared emergency medical services [1, 2, 6, 21, 22].

CONCLUSIONS

Introduction of a 24/7 primary PCI regional service (STEMI network) led to increased reperfusion treatment rates and improved accessibility of invasive diagnosis and treatment, resulting in reduced in-hospital and 1-year mortality among STEMI patients.

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Conflict of interest: *none declared*

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Wpływ wprowadzenia regionalnego programu terapii interwencyjnej zawału serca na wyniki leczenia pacjentów z zawałem serca z uniesieniem odcinka ST

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Streszczenie

Wstęp: Zabiegi pierwotnej przezskórnej interwencji wieńcowej (PCI) stanowią preferowaną metodę leczenia reperfuzyjnego pacjentów z zawałem serca z uniesieniem odcinka ST (STEMI) w stosunku do fibrynolizy, jeśli mogą być wykonane w odpowiednim przedziale czasowym, przez doświadczony personel, w ośrodku prowadzącym całodobowy dyżur hemodynamiczny. Opóźnienie związane z logistyką przekazania chorego z STEMI do pracowni hemodynamiki może być ograniczeniem dla tej metody terapii.

Cel: Celem pracy była ocena wyników leczenia pacjentów z STEMI hospitalizowanych w Szpitalu Powiatowym w Tarnowie w okresie przed i po wprowadzeniu dyżuru hemodynamicznego.

Metody: Rejestr obejmował 12-miesięczny Okres I (19.04.2004–19.04.2005) przed wprowadzeniem dyżuru hemodynamicznego i 15-miesięczny Okres II (8.08.2005–19.10.2006) po wprowadzeniu całodobowego dyżuru hemodynamicznego. Do badania włączono 226 pacjentów z STEMI (Okres STEMI I: n = 115, Okres STEMI II: n = 111). Pacjenci z grupy STEMI I byli leczeni zachowawczo (n = 59), farmakoinwazyjnie (farmakoterapia za pomocą połowy dawki lityku — alteplazy z pełną dawką abciximabu, a następnie transfer do ośrodka referencyjnego w celu wykonania koronarografii/PCI) (n = 32), a u części chorych zastosowano terapię lityczną streptokinazą (n = 24), natomiast w Okresie II u wszystkich pacjentów wykonano zabieg pierwotnej PCI w 1. dobie hospitalizacji. Grupy zostały poddane rocznej obserwacji, w czasie której oceniano częstość występowania zgonów z przyczyn sercowo-naczyniowych, ponownych zawałów serca niezakończonych zgonem i zabiegów rewaskularyzacyjnych PCI/pomostowania aortalno-wieńcowego.

Wyniki: Terapię reperfuzyjną zastosowano u 48,7% pacjentów z grupy STEMI I (leczenie farmakoinwazyjne: 27,8%, terapia lityczna: 20,9%) oraz u wszystkich pacjentów z grupy STEMI II (pierwotna PCI 100%). Śmiertelność wewnątrzszpitalna w grupie STEMI I była istotnie wyższa niż w grupie STEMI II (23,5% *vs*. 5,4%; p < 0,001), a w grupie chorych leczonych zachowawczo wynosiła 23,7%. Iloraz ryzyka (HR) dla Okresu II w porównaniu z Okresem I wyniósł 0,14 (95% CI 0,03–0,62; p = 0,009). Korzyść z zastosowania leczenia inwazyjnego utrzymywała się w obserwacji 12-miesięcznej (śmiertelność STEMI I *vs*. STEMI II: 26,1% *vs*. 9,0%; p = 0,001). Zastosowanie leczenia inwazyjnego skracało czas hospitalizacji pacjentów z STEMI.

Wnioski: Wprowadzenie regionalnego programu pierwotnej PCI opartego na sieci terapii interwencyjnej zawału pozwoliło na zwiększenie częstości leczenia reperfuzyjnego oraz zwiększenie dostępności do diagnostyki i terapii inwazyjnej. Po wprowadzeniu regionalnego programu pierwotnej PCI stwierdzono mniejszą śmiertelność wewnątrzszpitalną i roczną u pacjentów z STEMI.

Słowa kluczowe: zawał serca, rejestr, pierwotna przezskórna interwencja wieńcowa, zgon sercowo-naczyniowy, sieć terapii interwencyjnej zawału

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